



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2019-0103]

Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Proposed Additional Data Collection Fields and Modified Reporting Requirements; Final Notice

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces revised plans for additional data fields and modified reporting requirements for Assisted Reproductive Technology (ART) programs pursuant to the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). This notice also responds to public comments received in response to CDC's 2019 request for comment.

DATES: The requirements for the additional data fields and modified reporting requirements will be implemented for reporting year 2021.

FOR FURTHER INFORMATION CONTACT: Mithi Sunderam, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S107-2, Atlanta, Georgia 30341; Telephone: 1-800-232-4636; Email: ARTinfo@cdc.gov.

SUPPLEMENTARY INFORMATION: On November 6, 2019, CDC published a notice in the *Federal Register* (84 FR 59814) requesting comments on a plan proposing that ART programs collect additional information, listed below.

- i) For intended parents who are not oocyte source or pregnancy carriers under Section A (Patient Demographic Information): race/ethnicity.
- ii) For oocyte donors under Section D (Oocyte Source and Carrier Information): height, weight, smoking history, and other key pregnancy, diagnostic, and reproductive history (including number of prior pregnancies [ectopic, spontaneous abortions]; number of prior births [full term, preterm, live births, stillbirths]; history of prior ART cycles [fresh, frozen]; maximum follicle-stimulating hormone (FSH) level [value in mIU/mL]; and most

recent anti-müllerian hormone (AMH) level
[value in ng/mL, date]).

- iii) For both fresh embryo transfers and thawed embryo transfers, under Section H (Transfer Information): clinic names if oocyte retrievals took place in a clinic different from the one performing the transfer.

CDC also proposed changes in reporting responsibilities when multiple ART programs were involved in performing one cycle (such as different ART programs responsible for ovarian stimulation, oocyte retrieval, and/or embryo transfer), moving the reporting obligations from the ART program that accepts responsibility for embryo culture to the ART program that directs the clinical management of the cycle.

Public Comment Summary and Responses

CDC received three comments (two comments from researchers and one from the Society for Assisted Reproductive Technology) in response to its request for comment. Summaries of these comments and CDC's responses are provided below.

1. One commenter cautioned that embryos shipped between centers often arrive without retrieval information, such as

dates of retrieval. The commenter was otherwise supportive of collecting additional information for embryos shipped from different centers, as it would improve the accuracy of calculating cumulative success rates.

Response: CDC thanks the commenter for providing this comment. Accurate documentation of oocyte retrieval dates is important for establishing cumulative success rates. No changes were made to the reporting requirement.

2. A second commenter suggested using the term "intended parents" rather than "patients" for people who are not using their own oocytes or carrying a pregnancy. The commenter supported collection of additional information for oocyte donors and suggested expanding data collection to reflect changes in ART practice by collecting additional information (such as reproductive health and history, demographics, and detailed information on prior ART treatments) for all people involved in an ART cycle, including both intended parents and gestational carriers. The commenter also proposed that independent egg freezing clinics or companies that are not affiliated with ART clinics should be required to report their data. Finally, the commenter had many suggestions for improving the data collected by the Society for Assisted Reproductive Technology.

Response: CDC thanks the commenter for these suggestions. CDC agrees that the suggested terminology ("intended parents") is more accurate. No changes were made to the reporting requirements based on these comments; however, CDC will adopt the term "intended parents" where appropriate.

Any practice, program, or clinic providing ART services (such as egg freezing) is required to report its data to CDC whether or not it is affiliated with an ART clinic. Specifics about the reporting process and requirements are described in "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs" (80 FR 51811). Therefore, no changes to the reporting requirements are needed based on these comments.

3. A third commenter expressed concerns about the burden of additional data collection on reporting clinics. The commenter also noted that additional variables related to egg donors may not have an impact on pregnancy outcomes, which is the primary focus of FCSRCA. Additionally, the commenter noted that CDC's plan to collect information on race/ethnicity for intended parents using donor oocytes and gestational carriers was mainly for research purposes, as

these variables have no biological effect on pregnancy outcomes.

Response: CDC thanks the commenter for providing their feedback. Since the proposed additional information related to egg donors is already collected during the time of egg retrieval, CDC will instead link the information collected during egg retrieval from the clinic that performed the egg retrieval with information reported during donor egg or embryo transfer from the ART clinic performing the transfer. This can be achieved by transmitting the cycle identification number from the clinic that collected the donor egg to the clinic that provides care to the donor egg recipient. This will allow utilization of the data that are already collected to avoid additional burden on clinics. The details of the proposed linkage plan will be published separately in a different *Federal Register* notice before implementation.

CDC notes the commenter's feedback regarding collecting information on race/ethnicity for a small group of intended parents that do not use their own eggs or carry a pregnancy. Other demographic information such as date of birth, sex, and residency status are currently collected for this group; however, information on race/ethnicity is currently only collected for oocyte sources and pregnancy

carriers. Collecting information on race/ethnicity for both intended parents that do not use their own eggs or carry pregnancy, and for oocyte sources and pregnancy carriers, ensures consistency in demographic data collection. CDC also believes that this information allows the pregnancy success rates to reflect a complete set of demographics for intended parents and will help better understand disparities in utilization of ART services.

Please see the revised Appendix below for the new requirements.

Appendix – Notice for Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Additional Data Collection Fields and Modified Reporting Requirements:

A. Background

On August 26, 2015, CDC published a notice in the *Federal Register* (80 FR 51811) announcing the overall reporting requirements of the National ART Surveillance System (NASS). The notice described who shall report to HHS/CDC; the process for reporting by each ART program; the data to be reported; and the contents of the published reports. This data collection is approved under Office of Management and Budget Control Number 0920-0556, expiration date: 12/31/2024. The purpose of this notice published [INSERT

DATE OF PUBLICATION IN THE FEDERAL REGISTER] is to apply consistent data collection requirements to various treatment options, including certain rare situations, to improve quality of data. Effective for reporting year 2021, CDC is implementing the following changes to its data collection.

Section III. What to Report

Section A. Patient Demographic Information

Addition (for Intended Parents Who Are Not Oocyte Source or Pregnancy Carrier)

In addition to collecting information on race and ethnicity for oocyte source, sperm source, and pregnancy carrier as part of the current data collection system, CDC will also collect race and ethnicity information for intended parents who do not use their own oocytes (use donor eggs) and do not carry the pregnancy (use gestational carrier).

Specifically, this information will include i) Ethnicity (Hispanic, non-Hispanic, Refused, Unknown) and ii) Race (White, Black, Asian, Native Hawaiian/Pacific Islander, American Indian or Alaska Native, Refused, Unknown). CDC has added these questions to the patient profile in the beginning of the questionnaire to ensure consistency in demographic data collected and to allow the pregnancy success rates to reflect a complete set of demographics for intended parents. To reduce the reporting burden, the

system has been designed to pre-fill race/ethnicity of oocyte source, sperm source, or pregnancy carrier, if previously reported.

Section D. Oocyte Source and Carrier Information

Addition (for Oocyte Donors)

CDC has replaced its original plan to add several new data collection fields for oocyte donors which were to be obtained directly from ART programs. Instead, CDC plans to use the oocyte donor cycle identifying information to link and retrieve information about oocyte donors collected at the time of egg retrieval. When applicable, oocyte donor cycle identifying information will be transferred from the program involved in egg retrieval to the program involved in subsequent use of donor eggs. The details of the proposed linkage plan and the timeline for implementation of this plan will be published in a separate Federal Register notice before implementation.

Section H. Transfer Information

Addition (if Oocyte Retrieval Was Not Conducted at the Same Clinic as Transfer)

CDC will collect the name of the clinic in which the previous egg retrieval occurred for all fresh embryo transfers and thawed embryo transfers if the retrieval and transfer were completed at different clinics. Oocyte

retrieval dates are already being collected for all transferred embryos.

Reporting Requirement Modification

Section I. Who Reports

Sub-Section C. Reporting Responsibilities of ART Program

Modification (if More Than One Program is Involved in One Cycle)

Multiple ART programs involved in one cycle – Different ART programs responsible for ovarian stimulation, oocyte retrieval, and/or embryo transfer.

The following updated guidelines shall be used:

- a. The requirement to report cycles lies with the ART program that directs the clinical management of the cycle, which would include (but is not limited to) multiple aspects of the treatment such as patient selection, pre-treatment counseling and selection of the specific treatment protocol. The ART programs involved must have a method in place to ensure that these cycles can be prospectively reported by the ART program required to report them. In addition, all canceled cycles must be reported by the same ART program.

b. Cycles involving previously cryopreserved oocytes/embryos are to be reported by the ART program that accepts responsibility for thawing the oocytes/embryos.

Dated: June 7, 2022.

Angela K. Oliver,

Executive Secretary,

Centers for Disease Control and Prevention.

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